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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,858	03/30/2001	David W. Cannell	05725.0844-00	3869

22852 7590 11/28/2006

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,858

Applicant(s)

CANNELL ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30,32 and 34-150 is/are pending in the application.
- 4a) Of the above claim(s) 10-12,21-23,27,28,30,32,34,36 and 49-150 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,13-20,24-26,29,35 and 37-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The action mailed 8/25/06 is vacated in view of the supplemental below.

Examiner acknowledges receipt of request for extension of time filed 6/02/06, request for reconsideration filed 6/02/06. No claim is amended. Claims 1-30, 32 and 34-150 are pending.

Claims 10-12, 21-23, 27, 28, 30, 32, 34, 36 and 49-150 are withdrawn from consideration.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 16, 18, 19 and 48 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is dependent on claim 1 that has the proviso that the amino group on the polysaccharide is not substituted. Claim 16 does not exclude a polysaccharide having amino group that is substituted and claim 16 appears to be requiring substituted amino group.

Claims 18 and 19 require a substitution at C1 and C2 respectively of a saccharide unit with at least one amino group. C1 or C2 of the saccharide can only be substituted with one amino group. At least one amino group indicates that the minimum is one and the maximum is undefined that can be any number greater than 1. Explanation is respectfully requested.

Claim 48 says that the composition is heat activated. However, the composition after it is applied to hair is heat activated. Thus, it is confusing to refer to the composition as heat activated since a process of --- is not claimed. Explanation is respectfully requested.

Response to Arguments

3. Applicant's arguments filed 6/02/06 have been fully considered but they are not persuasive.

Applicant says that, "it is only when the at least one C5 to C7 saccharide unit is not a polysaccharide that the at least one amino group is chosen from unsubstituted amino group and substituted amino group." Applicant further states that language of claims 18 and 19 refers to the language of claim 1; and although the C1 and C2 may be substituted with only one amino group, the saccharide unit can be substituted with more than one amino group.

Response:

Claim 16 does not refer to a situation when the saccharide unit is not a polysaccharide. The proviso of claim 1 excludes claim 16. Similarly, claim 1 says with the proviso that the amino group on a C5 to C7 saccharide is unsubstituted and thus applicant's argument regarding claims 18 and 19, that the C1 and C2 may be substituted with only one amino group, the saccharide unit can be substituted with more than one amino group is not supported by the claim 1, which by the proviso excludes C5 to C7 saccharide that has substituted amino group.

Regarding claim 48, applicant argues that claim 48 is not confusing because "heat activated" is a property of the composition.

Response:

Examiner agrees with applicant that "heat activation" may be a property of the composition in the sense that the composition can be activated by heat. However, the claim phraseology can also mean that the composition is activated by heat and in the wise, the claim is

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ambiguous. An ambiguous claim has more than a single interpretation and thus vague and indefinite. The claim does not read on a property of the composition.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8, 13-16, 20, 24-26, 29, 35 and 45-47 remain rejected under 35 U.S.C. 102(b) as being anticipated by Woodin, Jr. et al. (US 5,494,533).

Woodin, Jr. discloses compositions and method of using said composition in personal cleansing (abstract). Exemplary compositions II-IV contain hydroxyethyl cellulose, polyquaternium and laurdimonium hydroxyethylcellulose, and other components. The polyquaternium and laurdimonium hydroxyethylcellulose are quaternary ammonium containing compounds that meet the limitation of claim 1 (a) and 2-8; while both the polyquaternium and the laurdimonium hydroxyethylcellulose meet the limitations claims 1 (a) and 2-8, the laurdimonium hydroxyethylcellulose meets the limitation of an amino polysaccharide in which the amino group is not substituted. Example III specifically has polyquaternium 24. Woodin also discloses that copolymers of saccharides and compatible synthetic monomers are employed in the cleansing composition, which meets the limitation of a compound comprising at least one C₅-C₇ saccharide units substituted with at least one amino group; the saccharides that are encompassed by the copolymers of saccharides and compatible synthetic monomers (compound) are glucose, galactose, mannose, arabinose, xylose, fucose, fructose, glucosamine, galactosamine

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and glucuronic acid (column 4, lines 44, 45 and 53-61). Polyquaternium 24 is present in an amount of 1.45% w/w in Example III and thus meets the limitation of claims 14 and 15. The laurdmonium hydroxyethylcellulose and glucosamine, which contain aldo-hexose amine sugars meet the limitations of claims 24-26. The composition of Woodin is packaged in container that would administer foamed compositions for topical applications (column 5, line 63 to column 7 line 26) and the composition is also formulated as foaming gels, foaming lotions and foaming scrubs and meets the limitations of claim 45. Woodin's compositions further comprise optional ingredients namely, conventional antibacterial agents, perfumes, dyes, preservatives, pigments, skin or hair moisturizers (column 7, line 35 to column 8 line 7); when the composition is formulated as a pharmaceutical, the composition would optionally contain pharmaceutically active agents such as analgesic, antibiotics and etc (column 8, lines 25-37). Regarding claim 29, it is noted that applicants' specification at page 7, line 20 defines the term "polymers" to include oligosaccharides. Therefore, Woodin meets the limitations of the designated claims.

Response to Arguments

6. Applicant's arguments filed 6/02/06 have been fully considered but they are not persuasive.

Applicant argues that a) the reliance on "laurdmonium hydroxyethylcellulose" is misplaced because US 5,962,015 to Delrieu, which was "previously cited by the Office, teaches that laurdmonium hydroxyethylcellulose is sold under the trademark CRODACL QL, and that CRODACL Q series of polymers all are quaternized cellulose polymers" (col. 4, line 64 to col. 5, line 38). Applicant concludes that since

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CRODACEL is a polysaccharide, it does not meet the requirements of the proviso in the claim 1.

That b) Woodin does not disclose combining glucosamine or galactosamine with a compound comprising at least two quaternary ammonium groups. That Woodin does not exemplify any copolymers comprising glucosamine or galactosamine in which the amino groups are unsubstituted.

Response:

Regarding a), Delrieu had not been cited as art in this application. However, Examiner agrees with applicant that CRODACEL is a polysaccharide according to Delrieu but the substituted amine group is not on the monosaccharide unit but is part of the hydroxyethyl cellulose unit and this cationic polymer specifically meets claim 1(a). Applicant's instant disclosure lists these types of cationic polymer as comprising at least two quaternary ammonium groups in paragraphs [0033] – [0039]; specifically paragraph [0036] of applicants published specification mentions these cationic polymers as being available from Croda. Furthermore, applicant's specification at paragraph [0036] lists polyquaternium 24 as a compound that comprises at least two quaternary ammonium groups. Thus, the CRODACEL or polyquaternium-11 (column 3, line 65 of Woodin) meet the limitation of "at least one compound at least two quaternary ammonium groups."

Regarding b) the amine groups in glucosamine and galactosamine are not substituted. Therefore, because, glucosamine and galactosamine do not have substituted amines, then the amine groups of Woodin's glucosamine and galactosamine are not substituted. Also, Woodin contemplates the use of mixtures (column 3, line 44, 53, 67) of anionic or non-ionic resins.

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7. Claims 1-9, 13, 16, 17, 20, 24-26, 29, 35, 39, 40 and 45-48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brode et al. (US 4,913,743).

Brode discloses compositions comprising glycosaminoglycans and “certain cationic polymers” and the compositions are used in personal care or medical applications (abstract; column 2, line 45-52); Brode specifically discloses using the composition in kericare, which Brode “describes the treatment or care of keratinous material, such as hair, skin, nails or other like material, and encompasses both medical and personal care applications” (column 11, lines 22-27). According to Brode, glycosaminoglycans are polysaccharides containing disaccharide repeating units of hexosamine and hexose or hexuronic acid, the glycosaminoglycans may also contain sulfate groups (column 3, lines 20-23). The cationic polymers may be polysaccharide such as polyquaternium 4, polyquaternium 10 and polyquaternium 24 (claim 10), polyalkylenimine, poly(meth)acrylamides, polyvinyl pyrrolidones, poly (meth)acrylates, diallyl dialkyl ammonium halides and condensation polymer (column 4, lines 16-64). The glycosaminoglycans are the compounds of the claimed invention that comprises at least one C₅-C₇ saccharide unit substituted with at least one amino group. The polyquaternium meets the limitation of the claimed compound comprising at least two quaternary ammonium groups. Run 40.1 to 40.9 contain 2.0-2.5 wt% and 0.1 wt% glycosaminoglycans (Table 1 in column 23). The personal care composition is in the form of skin cream, bath oils, gels and etc (column 11, line 33 to column 12 line 10). Brode’s composition further contains surfactants (column 12, lines 37-53), cleansers (column 12, lines 54-56), colorants, preservatives and moisturizers (column 12, lines 56-67), pH adjustment agents, emulsifiers, propellants and thickeners (column 12, line 67 to column 13 line 16). The thickeners of Brode are cellulose derivatives (column 13,

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lines 11-13). The cellulose derivatives listed in column 13, lines 11-13 comprise of aldo-hexose sugars and thus meets the limitation of the claimed invention further comprising additional sugar that is a polysaccharide in claim 40. Regarding claim 29, it is noted that applicants' specification at page 7, line 20 defines the term "polymers" to include oligosaccharides. Heat step is involved in the preparation of Brode's compositions (Example 2). Brode meets the limitations of the designated claims.

Response to Arguments

8. Applicant's arguments filed 6/02/06 have been fully considered but they are not persuasive.

Applicant argues that Brode cannot anticipate the claims because "Brode broadly teaches the combination of glycosaminoglycan and cationic polymer," and that "these categories are not the claimed invention. Applicant says that the claimed invention is directed to composition that comprises "at least one compound comprising at least two quaternary ammonium groups and (b) at least one compound comprising at least two quaternary ammonium group ... with the proviso ..., then the amino groups are unsubstituted. That the teaching of glycosaminoglycan does not identically describe the "compound of the claimed composition" polysaccharides in which the amino groups are substituted are not excluded in the same way as claim 1 excludes polysaccharides in which the amino groups are substituted.

Response:

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It is noted that there is no description of what a polysaccharide having substitution on the amino group is. An amide or acetylated amines are what they are, acetylated amines. A substituent on amine is generally alkyl groups and acetyl group is not alkyl. Therefore, the aminoglycans do not have substitution on the amine of the hexosamine.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14, 15, 37, 38 and 41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brode et al. (US 4,913,743) in view of Raaf et al. (US 4,743,442).

Brode is discussed above. Brode discloses composition comprising glycosaminoglycans and cationic polymer. The preferred amount of the glycosaminoglycans in the composition ranges from 0.0005 wt% to about 2 wt% (column 8, line 61) as opposed to the 0.01 to 10% recited in claim 37 and the 2 wt% of Brode intersects a point in the recited range. The amount of the cationic polymer is 2.5 wt% in Run 40.3 to 40.9 and this weight percent is one of the points in the recited range of 0.01% to 10% in claims 14 and 15. Brode is silent on the presence of monosaccharides such as glucose in the composition. Raaf discloses a composition comprising glucose, alginate, polyvinylpyrrolidone and other components for use as skin care and skin protection composition (Example 8). Brode's composition is also used as a skin care

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composition, which is formulated in a number of forms such as lotion, cream, gel and sprays (column 11, line 33 to column 12 line 10). Thus, both compositions are used for the same general purpose. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of Brode. One having ordinary skill in the art would have been motivated to combine the two compositions of Brode and Raaf to make a third composition that would be used for the same purpose of skin care (see *In re Kerkhoven*).

Response to Arguments

11. Applicant's arguments filed 6/02/06 have been fully considered but they are not persuasive.

Applicant reiterates that Brode's glycosaminoglycan has substitution on the amine and that Raaf does not remedy Brode's deficiency.

Response:

As noted above the acetylated hexosamine of the glycan is not substitution on the amine of the hexosamine since acetyl group is not equivalent to alkyl groups. There is no description in applicant's specification stating or naming the polysaccharides in which the amine group attached to the hexose or pentose or heptose units are not substituted and the type of substituents that are excluded or included. Alkyl groups are generally considered substituents on the amine

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nitrogen and acetylated amine is not a substituted amine. Therefore, by including the sugars of Raaf in the composition of Brode, all the limitations of the claims are met by the combined reference.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-9, 13-20, 37-40, 43, 44, 47 and 48 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-19, 26, 31-36, 38, 39, 42 and 43 of U.S. Patent No. 6,486,105. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but the examined application claim not is patentably distinct from each other because the claims are either anticipated by or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the saccharide

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in the examined claims is from C₅-C₇ while the saccharide in issued claim 1 is from C₃ to C₅ and C₅ is common to both; the compound comprising the at least two quaternary groups are the same in both the examined claims and the issued claims.

Response to Arguments

Regarding US 6,486,105:

Applicant's indication that a terminal disclaimer will be filed when allowable subject matter is identified has been noted. However, the rejection will be made/maintained in all office actions until the rejection is overcome.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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